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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61B 17/34

A1

(11) International Publication Number: WO 99/18866

(43) International Publication Date: 22 April 1999 (22.04.99)

(21) International Application Number: PCT/US98/21662

(22) International Filing Date: 14 October 1998 (14.10.98)

(30) Priority Data:
08/949,839 14 October 1997 (14.10.97) US

(63) Related by Continuation (CON) or Continuation-in-Part (CIP) to Earlier Application
US 08/949,839 (CIP)
Filed on 14 October 1997 (14.10.97)

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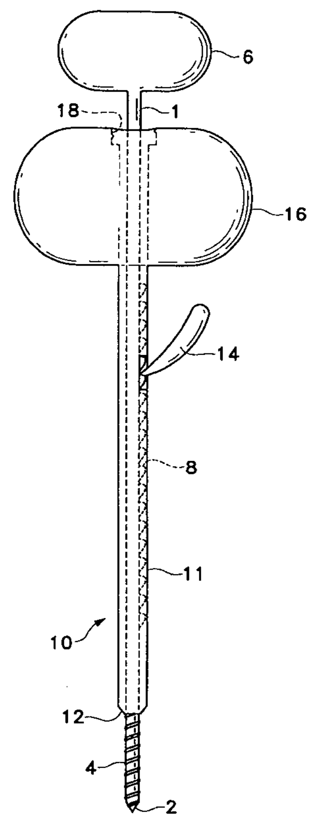
(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: PRECISION INSTRUMENTS FOR USE IN VERTEBROPLASTY

(57) Abstract

Precision depth guided instruments are provided for use in performing percutaneous implantation of hard tissue implant materials. A depth guided stylet includes a point adapted for piercing hard tissue, and preferably, self-tapping threads for self-tapping into hard tissue. The stylet may include an elongated rod having a first section having a first diameter, and a second section having a second diameter larger than the first diameter. A cannula for use with a depth guided stylet includes an elongated tube having first and second open ends adapted for a depth guided stylet to pass therethrough. The cannula may include a pawl passing through the elongated tube for ratcheting against a rack of gear teeth provided on the stylet. Alternatively, a camming mechanism may be pivotal arranged on the stylet. Upon pivoting the camming mechanism, the cam surface provides a driving force against the cannula to drive the cannula along the stylet. Another embodiment includes a stylet which is releasably fixed in a cannula so a threaded end of the stylet extends from the end of the cannula. The threaded end is used to draw the cannula into the desired implantation position, and a mechanism provides a sufficient mechanical advantage to retract the threaded end into the cannula. Methods of using the instruments are also described, as are kits which include the instruments and which are used to open a pathway into hard tissue.



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PRECISION INSTRUMENTS FOR USE IN VERTEBROPLASTY

CROSS-REFERENCE TO RELATED APPLICATIONS

The present application is continuation-in-part of copending U.S. application number 08/949,839, filed October 14, 1997. Additionally, this application is related to a copending U.S. application no 08/950,382 filed October 14, 1997.

TECHNICAL FIELD

The present invention relates to instruments for more accurately and safely controlling the placement thereof, during surgical procedures for the repair of hard tissue by injection of hard tissue implant materials. Procedures for such repair include hip augmentation, mandible augmentation, and particularly vertebroplasty, among others.

BACKGROUND ART

Polymethylmethacrylate (PMMA) has been used in anterior and posterior stabilization of the spine for metastatic disease, as described by Sundaresan et al., "Treatment of neoplastic epidural cord compression by vertebral body resection and stabilization." *J Neurosurg* 1985;63:676-684; Harrington, "Anterior decompression and stabilization of the spine as a treatment for vertebral collapse and spinal cord compression from metastatic malignancy." *Clinical Orthodpaedics and Related Research* 1988;233:177-197; and Cybulski, "Methods of surgical stabilization for metastatic disease of the spine." *Neurosurgery* 1989;25:240-252.

Deramond et al., "Percutaneous vertebroplasty with methyl-methacrylate: technique, method, results [abstract]." *Radiology* 1990;117 (suppl):352; among others, have described the percutaneous injection of PMMA into vertebral compression fractures by the transpedicular or paravertebral approach under CT and/or fluoroscopic guidance. Percutaneous vertebroplasty is desirable from the standpoint that it is minimally invasive, compared to the alternative of surgically exposing the hard tissue site to be supplemented with PMMA or other filler.

The general procedure for performing percutaneous vertebroplasty involves the use of a standard 11 gauge Jamshidi needle. The needle includes an 11 gauge cannula with an internal stylet. The cannula and stylet are used in conjunction to pierce the cutaneous

layers of a patient above the hard tissue to be supplemented, then to penetrate the hard cortical bone of the vertebra, and finally to traverse into the softer cancellous bone underlying the cortical bone.

A large force must be applied by the user, axially through the Jamshidi needle to drive the stylet through the cortical bone. Once penetration of the cortical bone is achieved, additional downward axial force, but at a reduced magnitude compared to that required to penetrate the cortical bone, is required to position the stylet/ tip of the cannula into the required position within the cancellous bone. If the force magnitude is not reduced appropriately, or if very soft bone is encountered, as is often the case with osteoporitic patients, the stylet and cannula can be accidentally and suddenly driven through the cortical bone on the opposite side of the vertebra. This is a very dangerous and potentially lethal situation in the case of vertebroplasty, since the aorta is located in close proximity to the anterior surface of at least the thoracic and lumbar vertebrae, and could easily be punctured by such an occurrence. Additionally, with regard to all vertebrae, the spinal cord is located medially of the pedicle, and could also be damaged by a piercing stylet.

Accordingly, there exists a need for a more controlled approach to the interior of a vertebral body for the performance of vertebroplasty and particularly, percutaneous vertebroplasty.

DISCLOSURE OF THE INVENTION

Disclosed are instruments for percutaneously accessing hard tissue to deliver a hard tissue implant material thereby. A depth guided stylet includes an elongated rod having first and second ends and a longitudinal axis. The first end terminates in a point adapted for piercing hard tissue. A handle is provided on the second end of the elongated rod for providing a mechanical advantage to a user in rotating the elongated rod about the rod's longitudinal axis.

Self-tapping threads preferably extend from the point along the elongated rod for a predetermined distance. The self-tapping threads are adapted to self-tap into hard tissue. A rack of gear teeth may be provided on the elongated rod in a location between the self-tapping threads and the second end of the elongated rod.

A cannula for use with a depth guided stylet is disclosed as including an elongated tube having first and second open ends adapted for a depth guided stylet to pass therethrough A pawl may extend through the elongated tube, for ratcheting with the gear teeth on the depth guiding stylet. A handle is attached to the second end of the elongated tube.

A kit for open a pathway into hard tissue, includes a depth guided stylet and a cannula according to the present invention. The kit may include a stylet having an elongated rod terminating in a point adapted for piercing hard tissue, and gear teeth located along the elongated rod. in which case the cannula may include an elongated tube having first and second open ends for allowing the depth guided stylet to pass therethrough, and a pawl extending through the elongated tube and adapted to ratchet with the gear teeth of the stylet

Alternatively, the kit may include a stylet having an elongated rod terminating in a point adapted for piercing hard tissue, and a camming mechanism pivotally mounted to provide a driving force to the cannula upon rotation thereof. In this case, the cannula includes an elongated tube having first and second open ends adapted for allowing the stylet to pass therethrough, and a surface adapted to interact with the camming mechanism for the transfer of the driving force.

In any case, the stylet preferably further includes self-tapping threads extending from the point along the elongated rod for a predetermined distance, which are adapted to self-tap into hard tissue. Further, a handle is provided on the second end of the stylet for providing a mechanical advantage to a user in rotating the elongated rod about its longitudinal axis. Likewise, a handle is provided on the second end of the elongated tube of the cannula.

Further, a connector is provided on the cannula handle for connecting the cannula to tubing following removal of the stylet from within the cannula. Alternatively, the connector may be arranged with an additional bore in the handle that allows connection with tubing and the commencement of injection of implant material before the stylet is completely removed from the cannula. Preferably the connector comprises a Luer lock fitting.

Another aspect of the present invention is the provision of a cannula having an elongated tube with a first section having a first diameter, and a second section having a

second diameter larger than diameter of the first section, to reduce the pressure requirements for effectively injecting the implant material. Additionally, the elongated rod of the stylet may be provide with a first rod section having a first rod diameter, and a second rod section having a second rod diameter larger than the first rod diameter, to closely follow the contour of the cannula..

A method of percutaneously implanting a hard tissue implant material is disclosed to include inserting a stylet and cannula percutaneously and through the soft tissues of an organism until abutting hard tissue; further inserting the stylet into a predetermined location within the hard tissue: and ratcheting a pawl mechanism against a rack of gear teeth to advance the cannula along the stylet to the predetermined position.

Alternatively, a method of percutaneously implanting a hard tissue implant material includes inserting a stylet and cannula percutaneously and through the soft tissues of an organism until abutting hard tissue; further inserting the stylet into a predetermined location within the hard tissue; and rotating a camming mechanism associated with the stylet and cannula to apply a driving force against the cannula to advance the cannula along the stylet to the predetermined position.

In either case, the stylet preferably includes self-tapping threads extending from an end thereof , in which case the further insertion of the stylet into the hard tissue is accomplished by torquing the stylet to thread the self-tapping threads into and through the hard tissue.

Additionally, the methods include withdrawing the stylet from within the cannula while maintaining the cannula in the predetermined position. the cannula may be connected to a source of implantable material wither after complete withdrawal of the stylet from within the cannula, or , alternatively, before the stylet has been completely withdrawn from the cannula.

Yet another aspect of the present invention includes a stylet having an elongated rod which is releasably fixed to a cannula. When in the fixed postion, a threaded end of the stylet extends from an end of the stylet. A first handle is fixed to the oppposite end of he stylet and radially extends from the elongated rod. A first engagement element is mounted radially externally of the elongated rod.

The cannula includes an elongated tube having first and second ends open and adapted the stylet to pass therethrough. A second handle is fixed to the second end of the

cannula and radially extends from the elongated tube. A second engagement element is mounted radially externally of the elongated tube and is adapted to interact with the first engagement element to releasably fix the elongated rod within the elongated tube.

The threads at the end of the stylet preferably are self-tapping threads. The first and second engagement elements preferably include mating threads fixed to the first and second handles, respectively. A connector is preferably mounted on the second handle and is adapted to connect the cannula to tubing or a syringe following removal of the stylet from within said cannula. In a preferred embodiment, the second engagement element comprises threads on said connector.

At least a portion of the first handle preferably provides a mechanical advantage of at least 2:1, more preferably at least 3:1, for driving the first engagement element with respect to the second engagement element.

Another method of percutaneously implanting a hard tissue implant material includes providing a stylet releasably fixed within a cannula and having a threaded end which extends beyond the cannula when fixed therein; inserting the stylet and cannula percutaneously and through the soft tissues of an organism until abutting hard tissue; torquing the stylet to engage the in the hard tissue to draw the stylet through the hard tissue and into a predetermined location within the hard tissue; and further torquing the stylet to draw the cannula into a predetermined location within the hard tissue.

Further, the stylet is reverse torqued with respect to the cannula to retract the threaded end into the cannula, while maintaining the cannula in the predetermined position. Next the stylet is completely removed from the cannula, preferably by sliding, after which a source of implantable material is connected to the cannula, and the material is implanted through the cannula.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a plan view of a preferred embodiment of the depth guided cannula and stylet according to the present invention;

Figure 2 is a plan view of another embodiment of a depth guided cannula and stylet according to the present invention;

Figure 3 is an additional view of the invention shown in Figure 2, with the cannula in a second preset position with respect to the stylet;

Figure 4 is yet another view of the embodiment shown in Figures 2-3, with the instruments having been rotated about their longitudinal axes by about ninety degrees;

Figure 5 shows another preferred embodiment according to the present invention which employs a pressure reduction feature;

Figure 6 shows another embodiment according to the present invention which employs a pressure reduction feature;

Figure 7 shows a variant of a connector placement according to the present invention;

Figures 8,9,10 and 11 are progressive views illustrating one of the more serious risks involved in a prior art procedure;

Figures 12, 13, 14, 15, 16 and 17 illustrate some of the advantages and risk reduction that are inherent in using the present invention;

Figure 18 is a plan view of yet another preferred embodiment of a depth guided cannula and stylet with the stylet tip extending from the cannula according to the present invention; and

Figure 19 is an additional view of the invention shown in Figure 18, with the stylet tip retracted within the cannula.

BEST MODE FOR CARRYING OUT THE INVENTION

The present invention substantially reduces several of the risk factors associated with the performance of percutaneous vertebroplasty. Additionally, the present invention enables a reduction in the amount of pressure which must necessarily be applied to the cannula, as well as the "filler" to be implanted via the cannula.

As noted above, the general procedure for performing percutaneous vertebroplasty involves the use of a standard 11 gauge Jamshidi needle, illustrated as reference numeral 100 in the prior art illustration of Figures 8-11. The needle 100 includes an 11 gauge cannula 101 with an internal stylet 102. The cannula 101 and stylet 102 are used in conjunction to pierce the cutaneous layers of a patient above the hard tissue to be supplemented, then to penetrate the hard cortical bone 103 of the vertebra, and finally to traverse into the softer cancellous bone 104 underlying the cortical bone.

A large force F must be applied by the user, axially through the Jamshidi needle to drive the stylet 102 through the cortical bone 103. Once penetration of the cortical bone

103 (through the pedicle of the vertebra in this example) is achieved, additional downward axial force, but at a reduced magnitude compared to that required to penetrate the cortical bone, is required to position the stylet/ tip of the cannula into the required position within the cancellous bone, as shown in a progression from Figure 9 to Figure 10. If the force magnitude is not reduced appropriately, or if very soft bone is encountered, as is often the case with osteoporitic patients, the stylet and cannula can be accidentally and suddenly driven through the cortical bone 103 on the opposite side of the vertebra. In one of the worse case scenarios, the stylet and cannula may continue traveling beyond the cortical bone and into the aorta 105, which is a potentially lethal situation. Another potential risk, due to the large driving forces required, is that the stylet 102 and cannula 101 could be driven askew and into the spinal cord 106 with the potential to cause permanent paralysis.

Because of the large forces required, it is not uncommon for the stylet and cannula to suddenly "break through" and make their pass through the cortical bone both very rapidly and very uncontrollably. Because of the speed with which such a break through can occur, it may be difficult if not impossible for the operator to react in time to reduce the driving force. Consequently, the cannula and stylet may be driven through the opposite cortical bone layer almost simultaneously.

The present invention overcomes these inherent risks by providing instruments, particularly cannulae, which can be driven through the cortical bone much more controllably and reliably. Less force is required to accomplish the placement of the instruments and, at the same time, the advancement of the instruments can be accomplished at a much slower and more controllable, consistent rate, e.g., as sequentially illustrated in Figures 12-17.

Turning to Figure 1, a preferred example of depth guided instruments will now be described. A stylet 1 is provided which has a length that is more than sufficient to span the distance from the epidermis of a patient to the cancellous bone tissue in the vertebra, in the preferred configuration. Typically the length of the stylet would be about three inches or greater, but lesser lengths may also be employed as well, depending on the size of the patient. Of course, if other hard tissues are to be accessed, the length of the stylet can be readily modified without departing from the inventive features of the present invention.

The stylet 1 is preferably made of a surgical grade stainless steel, but other known equivalent biocompatible metals and materials may be used for the same purpose. Ideally,

the stylet, or at least a distal end thereof. will be radiopaque so that it can be monitored using fluoroscopy, CT or other imaging techniques during the procedure to help determine the depth and location of the penetration.

A first or distal end of the stylet 1 ends in a point 2 which is sharp and adapted to penetrate hard tissue when axially loaded. Preferably, although not necessarily, the stylet 1 includes self-tapping threads 4 extending from the tip 2. The self-tapping threads 4 provide an advantage in that once the tip 2 has penetrated the cortical bone (e.g., see Figure 12), the operator of the stylet can than proceed to advance the stylet by torquing the stylet. which engages the self-tapping threads 4 in the cortical bone 103 and begins to screw the stylet 1 into the cortical bone. However, the stylet could, for example, use non-self tapping threads wherein a pre-tapped hole would be provided in the cortical bone prior to threading the stylet into position. Also. the stylet could have no threads whatsoever extending from the tip 2 and still employ the other advantageous features of the present invention.

The second or proximal end of the stylet preferably has a handle 6 molded or otherwise fixed thereto. to enable the operator to rotate or torque the stylet 1 about its longitudinal axis with a mechanical advantage, and also providing a surface against which to provide a pushing or axial force. The handle 6 is preferably molded of polycarbonate. However. any other materials which are durable. sterilizable and biofriendly. could be readily substituted. For example. the handle could be made from nylon or a host of other well-known plastics suitable for this purpose. or stainless steel. titanium. other biocompatible metals and ceramics.

A cannula 10 is provided which includes an elongated tubular structure 11 to be positioned in the cancellous bone for delivery of PMMA or other bone implant material therein. The tubular structure 11 of the cannula 10 is preferably made of a surgical grade of stainless steel, but may be made of known equivalent materials. similarly to the stylet 1 discussed above. Preferably, at least a distal end of the tubular structure is radiopaque. The tubular structure 11 has an inside diameter which is only slightly larger than the outside diameter of the stylet 1. so that the cannula may effortlessly pass axially over the stylet, while at the same time being supported and guided by the stylet. A first or distal end 12 of the cannula is preferably (but not necessarily) beveled to ease the penetration of the cannula through the cutaneous and soft tissues. and especially through the hard tissues.

A second or proximal end of the cannula preferably has a handle 16 molded or otherwise fixed thereto, to enable the operator to rotate, torque or push the cannula 10. The handle 16 is preferably molded of polycarbonate. However, any other materials which are durable, sterilizable and biofriendly, as discussed above with regard to handle 6, could be readily substituted.

The cannula 10 further includes a pawl 14 which extends through the wall of the cannula 11 and which can be ratcheted against a rack of gear teeth 8 provided on the stylet 1. Thus, the ratchet and pawl arrangement including pawl 14 and gear teeth 8 functions as a driving and control mechanism for the positioning, advancement and control of the cannula 10 with respect to the stylet 1 and vice versa. The pawl 14 can be ratcheted with respect to the rack 8 to move the cannula 10 up or down with respect to the stylet 1.

When a stylet is to be threaded or otherwise turned into position for guiding the cannula 10, the stylet may include gear teeth that circumscribe the stylet shaft so that the gear teeth are never out of alignment with the pawl 14 on the cannula 10, regardless of the rotational position of the stylet with respect to the cannula.

After screwing the stylet 1 into the desired position (e.g., the cancellous tissue of the vertebra as shown in Figures 12-14) in the hard tissue, as confirmed by viewing the position using an imaging technique referred to above, the operator proceeds to grasp the handle 6 so as to prevent the stylet from rotating further.

At the same time, the operator would ratchet the pawl 14 in an up and down fashion to advance the beveled end 12 of the cannula in a direction toward the point of the stylet 2 (Figure 15). The advancement of the cannula 10, and particularly the beveled end 12 are monitored using an imaging technique to ensure the proper placement of the cannula for injection of the PMMA or other hard tissue implant material. When the beveled end 12 is advanced to a position that is substantially flush with point 2 (Figure 16), the operator will cease the advancement of the cannula 10, since it will have reached its optimal position.

Upon disengaging the pawl 14 from the rack 8, the stylet 1 can then be reverse rotated out of the bone and then slid out from its position within the cannula 10, while maintaining the cannula 10 in its position, as shown in Figure 17.

An alternative method of inserting the cannula 10 would be to incrementally insert the stylet 1 and the cannula 10. More specifically, the operator would advance the stylet 1

only partially into the cortical bone 103 of the pedicle, and then advance the cannula 10 so as to be substantially flush or close to the tip 2, by ratcheting as described above. Then the operator would again advance the stylet 1 for a small distance through the cortical bone, stop the advancement and follow with advancement of the cannula 10 by the same increment. This type of incremental advancement could be continued until the tip 2 and the beveled end reach the same desired location as described above and shown in Figure 16. Incremental advancement may still further reduce the force that is necessary to be applied to advance the cannula 10 through the cortical bone 103. However, the incremental approach is more time consuming, which is a factor that must be considered in deciding whether or not to use the incremental approach.

Surrounding the second end of the tubular structure 11 is a connector 18 for linking the cannula 10 with a syringe or other tubular supply, for supplying the PMMA or other implantable material that is to be injected via tubular structure 11. Preferably, connector 18 is a Luer-lock type of connector, but other known connecting mechanisms may be successfully interchanged, e.g., a conventional threaded hole, a threads and locking nut arrangement, etc.

Figure 2 illustrates an alternative embodiment of a stylet 20 and cannula 30 for uses similar to those described with the embodiment shown in Figure 1. Stylet 20 includes a tip 2 and preferably, but not necessarily, self-tapping threads 4, just as in the embodiment of Figure 1. The materials employed to make the devices in Figure 2 are the same as those discussed above with regard to like parts in Figure 1.

The second or proximal end of the stylet 20 has a handle 26 molded, threaded or otherwise fixed thereto, to enable the operator to torque the stylet about its longitudinal axis with a force applied through a mechanical advantage, and to enable the operator to apply axial force to the stylet. Cannula 30 is provided and includes an elongated tubular structure 31 for positioning in the cancellous bone for delivery of PMMA or other bone implant material therein. The tubular structure 31 has an inside diameter which is only slightly larger than the outside diameter of the stylet 20, so that the cannula may effortlessly pass axially over the stylet, while at the same time being supported and guided by the stylet. A first or distal end 12 of the cannula is preferably (but not necessarily) beveled to ease the penetration of the cannula through the cutaneous and soft tissues, and especially through the hard tissues.

A second or proximal end of the cannula preferably has a handle 16 molded, threaded or otherwise fixed thereto, to enable the operator to rotate, torque or push the cannula 30.

A driving mechanism 36 is pivotally mounted to the stylet 20 via pin 37. At least one cam lobe 38 is positioned between handles 26 and 16 for application of force to handle 16 upon actuation. As shown in Figure 4, the driving mechanism preferably includes a pair of cam lobes located on opposite sides of the stylet shaft. Handle 26 is provided with a slot 35 which receives lever 39 therein. Lever 39 is rotatable about the pivot 37 to apply a rotational force to cam mechanism 38. Upon rotation of lever 39 from the position shown in Figure 2 to the position shown in Figure 3, the camming surface of cam mechanism 38 provides a driving force to drive cannula 20 from a first position shown in Figure 2 to a second position shown in Figure 3, where the end 12 of the cannula is substantially flush with the tip 2 of the stylet.

It is noted that both the embodiments of Figures 1 and 2 can be configured so that, when using a stylet having end threads, self-tapping or otherwise, the self-tapping may be covered to enable the stylet and cannula to be pushed through the soft tissues of the patient with less drag and less damage to the soft tissues of the patient than would result if the tapping threads were exposed during this part of the procedure e.g., see the configuration shown in Figure 3.

Once the stylet tip 2 has penetrated the cortical bone, the operator can then retract the cannula 10,30 from the tip 2 to expose the threads 4 to be threaded into the bone. For this step, it is noted that retraction of the embodiment in Figure 2 is much faster than that of Figure 1, requiring only a simple rotation of handle 39 as compared to a significant amount of ratcheting of the pawl 14.

Once in the preset position shown respectively in Figures 1 and 2, the stylet is configured to be passed through the cortical bone and into the desired position, either by the use of self-tapping threads 4 or other means discussed above, including simply piercing an unthreaded stylet through the cortical bone. When threads are used, handle 26 is next torqued in a clockwise direction to engage the self-tapping threads 4 in the cortical bone and begin screwing the stylet 1,20 through the cortical bone and into the desired position in the cancellous bone. After screwing the stylet 1, 20 into the desired position (e.g., the cancellous tissue of the vertebra) in the hard tissue, as confirmed by viewing the position

using an imaging technique referred to above, the operator proceeds to move the cannula 10,30 into position in the manners already described.

Although the use of a stylet having no threads for threading into the bone does not provide the same measure of safety and control for advancement of the stylet, the embodiments of Figures 1 and 2 would still provide substantially the same factors of safety for advancement of the respective cannulae disclosed therein.

Similar to the above description with regard to the embodiment in Figure 1, an alternative method of inserting the cannula 30 would be to incrementally insert the stylet 20 and the cannula 30. More specifically, the operator could thread or otherwise insert the stylet 20 only partially into the cortical bone 103 of the pedicle, and then advance the cannula 30 so as to be substantially flush or close to the tip 2 as described above. Then the operator would release the camming surface 38 to position lever 39 as shown in Figure 2, and then again advance the stylet for a small distance through the cortical bone, stop the advancement and follow with advancement of the cannula 30 by the same increment. This type of incremental advancement could be continued until the tip 2 and the beveled end reach the same desired location as described above. Incremental advancement may still further reduce the force that is necessary to be applied to advance the cannula 30 through the cortical bone 103 and thereby increase the safety factor during insertion of the cannula 30. However, the incremental approach is more time consuming, which is a factor that must be considered in deciding whether or not to use the incremental approach.

Surrounding the second end of the tubular structure 31 is a connector 18 for linking the cannula 30 with a syringe or other tubular supply, for supplying the PMMA or other implantable material that is to be injected via the tubular structure 31.

Figure 5 shows a variant of the embodiment described with regard to Figure 1. In order to reduce the substantial amount of pressure that is required to inject PMMA or other bone filler through a standard sized cannula, Figure 5 shows a modification in which the cannula 70 includes a modified tubular structure design. The first or distal portion 71 of the tubular structure is of the same dimensions as the embodiment of Figure 1. The second or proximal portion 72 of the cannula 70, however, has a substantially larger diameter than that of the first portion 71. Preferably, the diameter of second portion 72 is about twice the diameter of first portion 71, although any increase in the diameter of second portion 72

over that of the first portion 71 will decrease the pressure requirement for effective delivery of the material to be implanted.

The first and second portions 71,72 have approximately equal lengths, but this is governed by the anatomy of the site to be accessed. In the "average" percutaneous vertebroplasty situation, the first portion 71 is required to be about 1.5" long, as this is the length that is needed for traversing the cortical bone of the pedicle. Thus, the first portion should not be significantly enlarged due to the size constraints of the pedicle, the safety risks to the spinal column and aorta which are increased when the cannula size is increased intravertebrally, and by the desire to remove as little bone as possible when entering with the stylet and cannula, among other factors.

However, the portion of the cannula which will occupy the soft tissues can be significantly expanded without substantially adversely effecting the patient. Given the benefits of reducing the required injection pressure and ensuring a better delivery of the bone implant material, such a modification becomes a viable option.

The devices shown in Figure 5 operate similarly to that of the embodiment of Figure 1, i.e., a pawl 14 passes through a wall of the cannula 70, preferably in the second portion 72. The pawl 14 can be ratcheted against a rack of gear teeth 8 provided on the stylet 60. Thus, the ratchet and pawl arrangement including pawl 14 and gear teeth 8 functions as a driving and control mechanism for the positioning, advancement and control of the cannula 70 with respect to the stylet 60 and vice versa. The pawl 14 can be ratcheted with respect to the rack 8 to move the cannula 70 up or down with respect to the stylet 60.

When a stylet is to be threaded or otherwise turned into position for guiding the cannula 10, the stylet may include gear teeth that circumscribe the stylet shaft so that the gear teeth are never out of alignment with the pawl 14 on the cannula 10, regardless of the rotational position of the stylet with respect to the cannula. In the embodiment shown in Figure 5, the stylet 60 is designed to closely follow the contour of the cannula 70 to provide a close guidance along the full length of the cannula 70. While the first portion 61 is substantially of the same diameter as the stylet 1 in Figure 1, the second portion 62 must be substantially larger, preferably twice the diameter of the first portion, to follow the contours of the portion 72 of the cannula. However, a stylet having only a single diameter throughout, e.g., a diameter equal to that of portion 61 could be employed. Such an

embodiment would require modification of the pawl 14 to extend further radially inward so as to interact with gear teeth that would be placed on a smaller diameter stylet. Similar to the embodiment of Figure 1, the ratcheting of the pawl against gear teeth 8 provides a driving and control mechanism for the positioning, advancement and control of the cannula 70 with respect to the stylet 60 and vice versa.

Handle 76 is substantially similar to handle 16 in its design, material, and connection with the tubular structure 71. However, due to the increased diameter of the second portion 72 of the tubular structure 70 and the second portion 62 of the stylet 60, the handle 76 must also have an increased hole through which the second portion 62 of the stylet 60 passes. Handle 66 is substantially similar to handle 6 in its design, material, and connection with the stylet 60, although if molded around the stylet 60, the handle 66 must also have a larger hole than handle 6 to pass the enlarge diameter of the stylet portion 62.

Surrounding the second end of the tubular structure of the cannula 70 is a connector 78 for linking the cannula 70 with a syringe or other tubular supply, for supplying the PMMA or other implantable material that is to be injected via the cannula 70. Preferably, connector 78 is a Luer-lock type of connector, but other known connecting mechanisms may be successfully interchanged, e.g., a conventional threaded hole, a threads and locking nut arrangement, etc.

The variant shown in Figure 6 combines the advantages of the embodiment shown in Figures 2-4 with the pressure reducing concept described above with respect to Figure 5. The variant shown in Figure 6 uses the same stylet 20 as that shown in Figure 2, but has a cannula 90 which includes a modified tubular structure design. However, a stylet that generally follows the contours of cannula 90 could alternatively be used. The first or distal portion 91 of the tubular structure is of the same dimensions as the cannula 30. The second or proximal portion 92 of the cannula 90, however, has a substantially larger diameter than that of the first portion 91, similar to the cannula in Figure 5. Preferably, the diameter of second portion 92 is about twice the diameter of first portion 91, although any increase in the diameter of second portion 92 over that of the first portion 91 will decrease the pressure requirement for effective delivery of the material to be implanted.

The devices shown in Figure 6 operate similarly to that of the embodiment of Figures 2-5 with the added advantage of reduction of the pressure required to deliver the implant material.

Handle 93 is substantially similar to handle 16 in its design, material, and connection with the tubular structure 92. However, due to the increased diameter of the second portion 92 of the tubular structure 90, the handle 93 must also have an increased hole through which the second portion 92 of the cannula 90 passes.

Surrounding the second end of the tubular structure of the cannula 90 is a connector 78 for linking the cannula 90 with a syringe or other tubular supply, for supplying the PMMA or other implantable material that is to be injected via the cannula 90. Preferably, connector 78 is a Luer-lock type of connector, but other known connecting mechanisms may be successfully interchanged, e.g., a conventional threaded hole, a threads and locking nut arrangement, etc. The driving control mechanism functions essentially the same as that described above with regard to Figures 2-4.

Figure 7 shows a variation in the placement of a connector 18' for linking the cannula 10' with a syringe or other tubular supply, for supplying the PMMA or other implantable material that is to be injected via tubular structure 11'. This variation can also be employed with any of the earlier described cannula embodiments. Preferably, connector 18' is a Luer-lock type of connector, but other known connecting mechanisms may be successfully interchanged, e.g., a conventional threaded hole, a threads and locking nut arrangement, etc.

In this variant, the connector 18' is provided on the surface of handle 16' at a position out of line with the longitudinal axis of the cannula 11'. Thus, an additional bore 19 is provided in handle 16' to join the connector 18' with the internal bore of the cannula 10'. The connector 18' may be positioned at any convenient angle to the longitudinal axis of the cannula 11' and located at any convenient location on the surface of handle 16'. This variation enables pressure to be applied, and even the beginning of injection of the implant material, while the stylet 1 is still at least partially inserted within the cannula 11'. Additionally, this arrangement would allow the bore 19 to be of a significantly larger diameter than the bore of the cannula 10' to give an even further reduction in the amount of pressure that need be applied to implant the implantable material. A seal 21 (e.g., an o-ring or equivalent) may be provided to help maintain a pressure seal between the stylet 1 and the handle 16' in the event that the stylet 1 is still within the handle 16' when injection begins. Additionally or alternatively, threads 21' may be provided in handle 16' to accept a plug to positively seal the handle 16' during injection.

Figure 18 shows a further embodiment which is configured for a more simplified procedure for placing the cannula in situ. In this embodiment, the cannula 110 and stylet 111 are threadably or otherwise removable connected for placement in the desired implantation site as a unit. The initial placement is the same as that described with the previous embodiments, as the unit is initially placed by percutaneously driving it through the skin and further driving through any soft tissues that may need to be traversed, then screwing the stylet 111 in the desired postion (e.g., the cancellous tissue of the vertebra or other hard tissue or implantation site). The driving and screwing procedures are facilitated by the provision of handles 116 and 120 which are preferably formed of the same materials discussed above with regard to handles 6 and 16, for example. Particularly, the screwing is performed by torquing the handle 120 or a combination of both handles 120 and 116.

Upon confirmation that the stylet tip 2 has been placed into the implantation site, using an imaging technique referred to above, it is determined whether the cannula tip 12 is positioned appropriately. If the cannula tip 12 needs to be advanced further, the same screwing procedure is repeated to draw the cannula into the desired postion by the action of the screw threads 4.

The threads 4 are preferably self-tapping threads 4 extending from the tip 2. The self-tapping threads 4 provide an advantage in that once the tip 2 has penetrated the cortical bone (e.g., see Figure 12), the operator of the stylet can than proceed to advance the stylet by torquing the stylet, which engages the self-tapping threads 4 in the cortical bone 103 and begins to screw the stylet 1 into the cortical bone. However, the stylet could, for example, use non-self tapping threads wherein a pre-tapped hole would be provided in the cortical bone prior to threading the stylet into position.

Once a confirmation has been made of the proper positioning of the cannula tip 12, the next step is the removal of the stylet 111. Removal is performed by grasping and steadying the handle 116, while torquing the handle 120 with respect thereto. Handle 120 is fixed to stylet 111 at 121 by molding, gluing or other fixation means or a combination thereof. Handle 120 is threadably (or by some other controllably releasable connection) connected to the cannula by mating threads 122 provided in handle 120 and 124 fixed in some manner to the cannula 110. In the example shown in Figure 18, threads 124 serve a dual purpose in fixing the cannula 110 and stylet 111 together, as well as being provided as part of a connection site 118 for the source of implantable material, i.e., for linking the

cannula 110 with a syringe or other tubular supply, for supplying the PMMA or other implantable material that is to be injected. Preferably, the connector 118 is a Luer-lock type of connector, but other known connecting mechanisms may be successfully interchanged, e.g., a conventional threaded extension; a bayonet-type arrangement, etc.

Further, the connecting threads for connecting the stylet to the cannula need not be the same as those used in connecting the cannula 110 to the implant material source, although this arrangement is preferred. For example, mating threads may be provided directly between the handles 116 and 120. However, it has been discovered that withdrawal of the threads 4 into the cannula 110 sometimes incurs significant binding forces, as bone chips and/or other tissue and material that accumulates between the threads 4 during the torquing of the stylet into the implant site, remain between the threads and effectively render the outside diameter of the stylet larger than the inside diameter of the cannula tip 12. Thus, it is important to provide a handle or driver that provides a significant advantage to the operator to torque the stylet with sufficient force to shear any extending material form the exterior of the threads 4 to enable the threads 4 to enter the cannula 110.

In the embodiment of Figure 18 an extended portion 126 of the handle 120 is provided to effectively increase the mechanical advantage of the handle during torquing, by increasing the effective lever arm. The effective lever arm in this example is defined by the ratio of the distance D, defining the distance from the exterior of extension 126 to the central axis C about which rotation occurs, to the distance d, defining the distance from the exterior of threads 124 to the central axis C. In order to ensure a smooth and positive withdrawal of the threads 4 from the implant site and through the cannula 110, it is preferred to employ a device having a mechanical advantage defined by a lever arm D/d of at least about 2:1, more preferably about 3:1 and most preferably greater than about 3:1.

The extension 126 may be substantially cylindrically formed but need not be. It may be formed to have a substantially square cross section or as a pair of diametrically opposed levers, a three spoke pattern of extension levers, or many other configurations which effectively increase the mechanical advantage of the handle. The extension 126 may be formed as separate piece which is then fixed to the handle 120 as indicated by the phantom line 126'. Alternatively, the entire handle 120 can simply be formed to extend

out to the dimensions depicted by the extension 126 in Figure 18, although this is not a preferred arrangement due to the increased bulk, weight, etc.

Figure 19 shows the embodiment of Figure 18 after the threads 124 have been completely disengaged from threads 122. As shown, the threads are preferably of a length substantially equal to the length of the protrusion of the stylet beyond the cannula, i.e., the length of threads 4 at the tip end of the stylet that extend beyond the cannula in the "unit" configuration shown in Figure 18. However, a slight remaining protrusion of the tip end 2 after separation of the threads 122 and 124 may also be acceptable. At this time the threads 4 will have been sufficiently stripped of external tissue so that complete removal of the stylet 111 from the cannula 110 can be relatively effortlessly performed by a simple sliding action through pulling on handle 120, 126, while steadying the handle 116.

After complete removal of the stylet 111 from the cannula 110 a syringe, tube or other connector for supplying implant material (not shown) is fixed to the connector 118 .

In order to reduce the substantial amount of pressure that is required to inject PMMA or other bone filler through a standard sized cannula, the cannula 110 may be modified and configured similarly to that shown in Figure 5, so that the first or distal portion of the tubular structure is of the same dimensions as the embodiment of Figure 18. The second or proximal portion however, would be formed to have a substantially larger diameter than that of the first portion.

Although there have been described above a specific arrangement of devices for percutaneous delivery of a bone implant material, with a limited selected number of alternative embodiments in accordance with the invention for the purpose of illustrating the manner in which the invention may be used to advantage, it will be appreciated that the invention is not limited thereto. Accordingly, any and all modifications, variations or equivalent arrangements which may occur to those skilled in the art should be considered to be within the scope of the invention as set forth in the claims which follow.

CLAIMS

What is claimed is:

1. A cannula for use with a depth guided stylet, said cannula comprising:

an elongated tube having first and second ends, said first and second ends being open and adapted for a depth guided stylet to pass therethrough; and

a pawl extending through said elongated tube, said pawl adapted to ratchet with a rack of gear teeth provided on the depth guiding stylet.

2. The cannula of claim 1, further comprising a handle attached to said second end of said elongated tube.

3. A kit adapted to open a pathway into hard tissue, comprising:

a depth guided stylet comprising:

an elongated rod having first and second ends and a longitudinal axis, said first end terminating in a point adapted for piercing hard tissue; and

gear teeth located along said elongated rod; and

a cannula comprising:

an elongated tube having first and second ends, said first and second ends being open and adapted for said depth guided stylet to pass therethrough; and

a pawl extending through said elongated tube, said pawl adapted to ratchet with said gear teeth.

4. The kit of claim 3, further comprising:

self-tapping threads extending from said point along said elongated rod for a predetermined distance, said self-tapping threads adapted to self-tap into hard tissue.

5. The kit of claim 3, wherein said depth guided stylet further comprises a handle provided on said second end for providing a mechanical advantage to a user in rotating said elongated rod about said longitudinal axis.

6. The kit of claim 3, wherein said cannula further comprises a handle provided on said second end of said elongated tube.

7. The kit of claim 6, further comprising a connector on said handle for connecting said cannula to tubing following removal of said stylet from within said cannula.

8. The kit of claim 7, wherein said connector comprise a Luer lock fitting.

9. The kit of claim 7, further comprising a bore through at least a portion of said handle, said bore connecting said connector with said elongated tube.

10. The kit of claim 9, wherein a longitudinal axis of said bore is non-parallel with and intersects a longitudinal axis of said elongated tube.

11. The kit of claim 3, wherein said elongated tube comprises a first section having a first diameter, and a second section having a second diameter larger than said first diameter; and

wherein said first section is closer than said second section to said first end of said elongated tube.

12. The kit of claim 11, wherein said elongated rod comprises a first rod section having a first rod diameter, and a second rod section having a second rod diameter larger than said first rod diameter.

13. A stylet, comprising:

an elongated rod having first and second ends and a longitudinal axis, said first end terminating in a point adapted for piercing hard tissue; and

a camming mechanism pivotally mounted to provide a driving force to a cannula upon rotation thereof.

14. The stylet of claim 13, further comprising a handle attached to said second end of said elongated rod.

15. The stylet of claim 13, further comprising:

self-tapping threads extending from said point along said elongated rod for a predetermined distance, said self-tapping threads adapted to self-tap into hard tissue.

16. A kit adapted to open a pathway into hard tissue, comprising:

a depth guided stylet comprising:

an elongated rod having first and second ends and a longitudinal axis, said first end terminating in a point adapted for piercing hard tissue; and

a camming mechanism pivotally mounted to provide a driving force to a cannula upon rotation thereof; and

a cannula comprising:

an elongated tube having first and second ends, said first and second ends being open and adapted for said depth guided stylet to pass therethrough; and

a surface adapted to interact with said camming mechanism for the transfer of said driving force.

17. The kit of claim 16, further comprising:

self-tapping threads extending from said point along said elongated rod for a predetermined distance, said self-tapping threads adapted to self-tap into hard tissue.

18. The kit of claim 16, wherein said depth guided stylet further comprises a handle provided on said second end for providing a mechanical advantage to a user in rotating said elongated rod about said longitudinal axis.

19. The kit of claim 16, wherein said cannula further comprises a handle provided on said second end of said elongated tube, said surface being located on said handle of said cannula.

20. The kit of claim 19, further comprising a connector on said handle for connecting said cannula to tubing following removal of said stylet from within said cannula.

21. The kit of claim 20, wherein said connector comprise a Luer lock fitting.

22. The kit of claim 20, further comprising a bore through at least a portion of said handle, said bore connecting said connector with said elongated tube.

23. The kit of claim 22, wherein a longitudinal axis of said bore is non-parallel with and intersects a longitudinal axis of said elongated tube.

24. The kit of claim 16, wherein said elongated tube comprises a first section having a first diameter, and a second section having a second diameter larger than said first diameter; and

wherein said first section is closer than said second section to said first end of said elongated tube.

25. The kit of claim 24, wherein said elongated rod comprises a first rod section having a first rod diameter, and a second rod section having a second rod diameter larger than said first rod diameter.

26. A method of percutaneously implanting a hard tissue implant material comprising:

inserting a stylet and cannula percutaneously and through the soft tissues of an organism until abutting hard tissue;

further inserting the stylet into a predetermined location within the hard tissue; and

ratcheting a pawl mechanism against a rack of gear teeth to advance the cannula along the stylet to the predetermined position.

27. The method of claim 26, wherein the stylet includes self-tapping threads extending from an end thereof and said further inserting the stylet comprises torquing the stylet to thread the self-tapping threads into and through the hard tissue:

28. The method of claim 26, further comprising:

withdrawing the stylet from within the cannula while maintaining the cannula in the predetermined position.

29. The method of claim 28, further comprising:

connecting the cannula to a source of implantable material after said withdrawing of the stylet.

30. The method of claim 28, further comprising:

connecting the cannula to a source of implantable material before the stylet has been completely withdrawn from the cannula.

31. A method of percutaneously implanting a hard tissue implant material comprising:

inserting a stylet and cannula percutaneously and through the soft tissues of an organism until abutting hard tissue;

further inserting the stylet into a predetermined location within the hard tissue; and

rotating a camming mechanism associated with the stylet and cannula to apply a driving force against the cannula to advance the cannula along the stylet to the predetermined position.

32. The method of claim 31, wherein the stylet includes self-tapping threads extending from an end thereof and said further inserting the stylet comprises torquing the stylet to thread the self-tapping threads into and through the hard tissue:

33. The method of claim 31, further comprising:

withdrawing the stylet from within the cannula while maintaining the cannula in the predetermined position.

34. The method of claim 33, further comprising:

connecting the cannula to a source of implantable material after said withdrawing of the stylet.

35. The method of claim 33, further comprising:

connecting the cannula to a source of implantable material before the stylet has been completely withdrawn from the cannula.

36. A kit adapted to open a pathway into hard tissue, comprising:

a stylet comprising:

an elongated rod having first and second ends and a longitudinal axis, said first end terminating in a point adapted for piercing hard tissue;

threads extending from said point along said elongated rod for a predetermined distance, said threads adapted to engage with the hard tissue;

a first handle fixed to said second end and radially extending from said elongated rod, with respect to a central axis of said elongated rod; and

a first engagement element mounted radially externally of said elongated rod;

a cannula comprising:

an elongated tube having first and second ends, said first and second ends being open and adapted for said stylet to pass therethrough;

a second handle fixed to said second end of said cannula and radially extending from said elongated tube, with respect to a central axis of said elongated tube; and

a second engagement element mounted radially externally of said elongated tube and adapted to interact with said first engagement element to releasably fix said elongated rod within said elongated tube.

37. The kit of claim 36, wherein said threads extend beyond said first end of said elongated tube when said first and second engagement elements are engaged to releasably fix said elongated rod within said elongated tube.

38. The kit of claim 36, wherein said threads comprise self-tapping threads.

39. The kit of claim 36, wherein said first engagement element comprises engagement threads fixed to said first handle and said second engagement element comprises engagement threads which mate with said engagement threads fixed to said first handle.

40. The kit of claim 36, further comprising a connector on said second handle, said connector adapted to connect said cannula to tubing or a syringe following removal of said stylet from within said cannula.

41. The kit of claim 39, further comprising a connector on said second handle, said connector adapted to connect said cannula to tubing or a syringe following removal of said stylet from within said cannula, wherein said engagement threads are provided on said connector.

42. The kit of claim 36, wherein at least a portion of said first handle provides a mechanical advantage of at least 2:1 for driving said first engagement element with respect to said second engagement element.

43. The kit of claim 42, wherein said mechanical advantage is at least 3:1.

44. A method of percutaneously implanting a hard tissue implant material comprising:

providing a stylet releasably fixed within a cannula and having a threaded end which extends beyond the cannula when fixed therein;

inserting the stylet and cannula percutaneously and through the soft tissues of an organism until abutting hard tissue;

torquing the stylet to engage the in the hard tissue to draw the stylet through the hard tissue and into a predetermined location within the hard tissue; and

further torquing the stylet to draw the cannula into a predetermined location within the hard tissue.

45. The method of claim 44, further comprising:

reverse torquing the stylet with respect to the cannula to retract the threaded end into the cannula, while maintaining the cannula in the predetermined position.

46. The method of claim 45, further comprising:

further removing the stylet from the cannula to completely separate the stylet from within the cannula.

47. The method of claim 46, wherein said further removing comprises sliding the stylet out of the cannula.

48. The method of claim 46, further comprising:

connecting a source of implantable material to the cannula, and implanting the implantable material through the cannula.

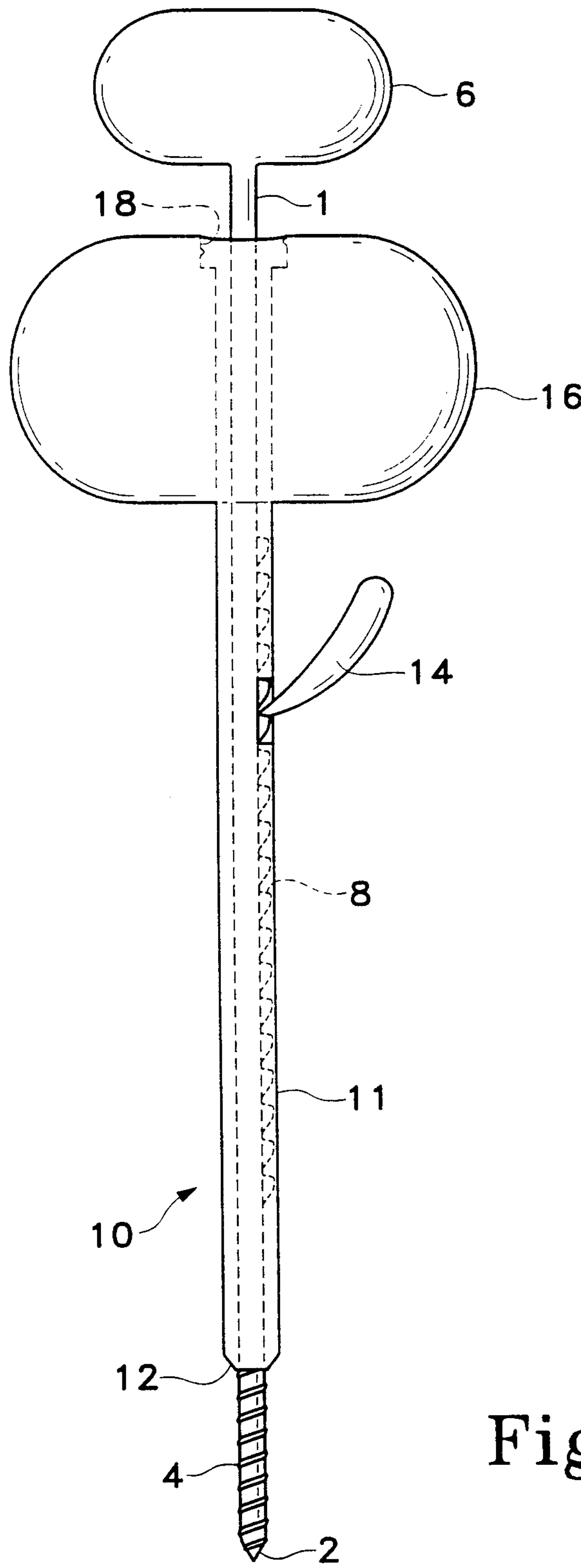

Fig. 1

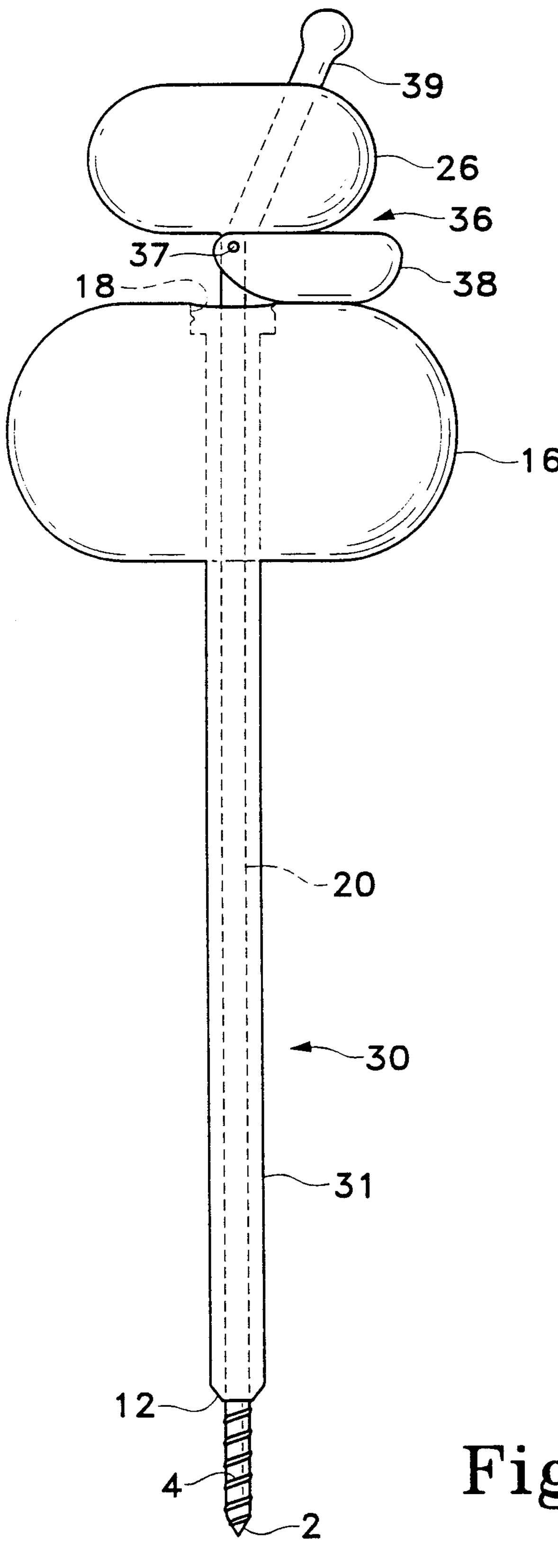

Fig. 2

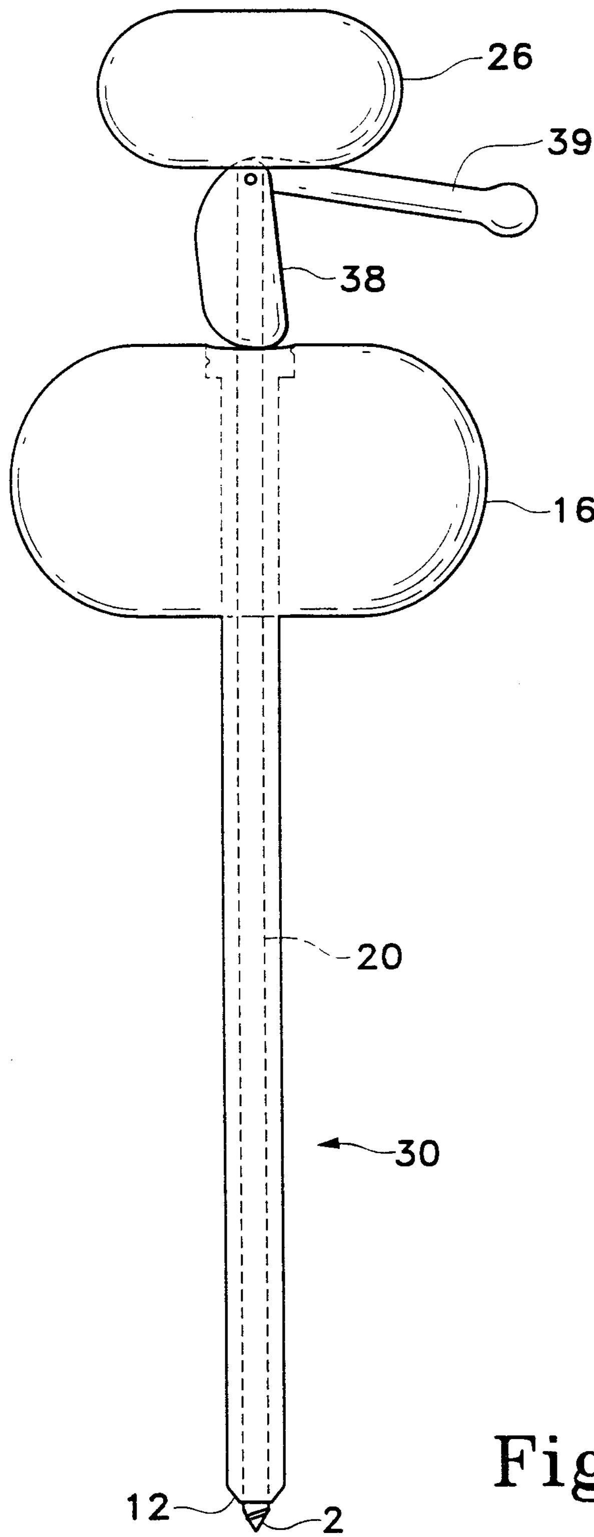

Fig. 3

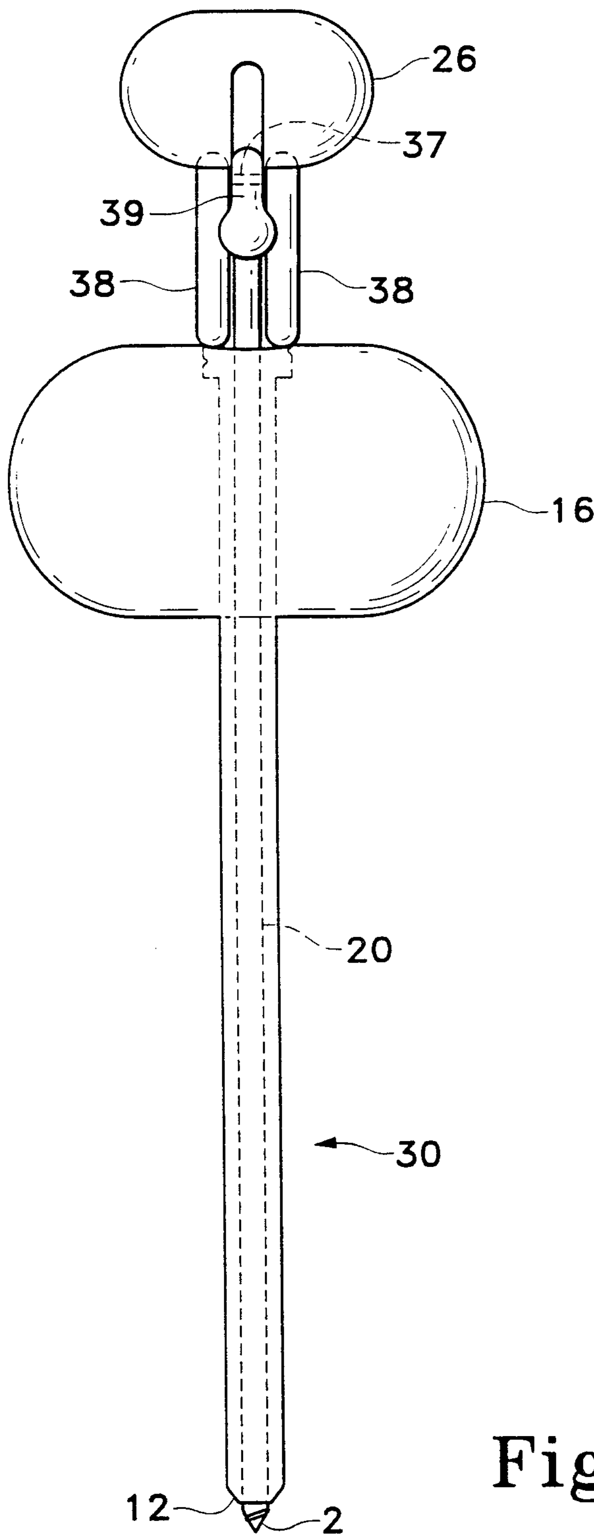

Fig. 4

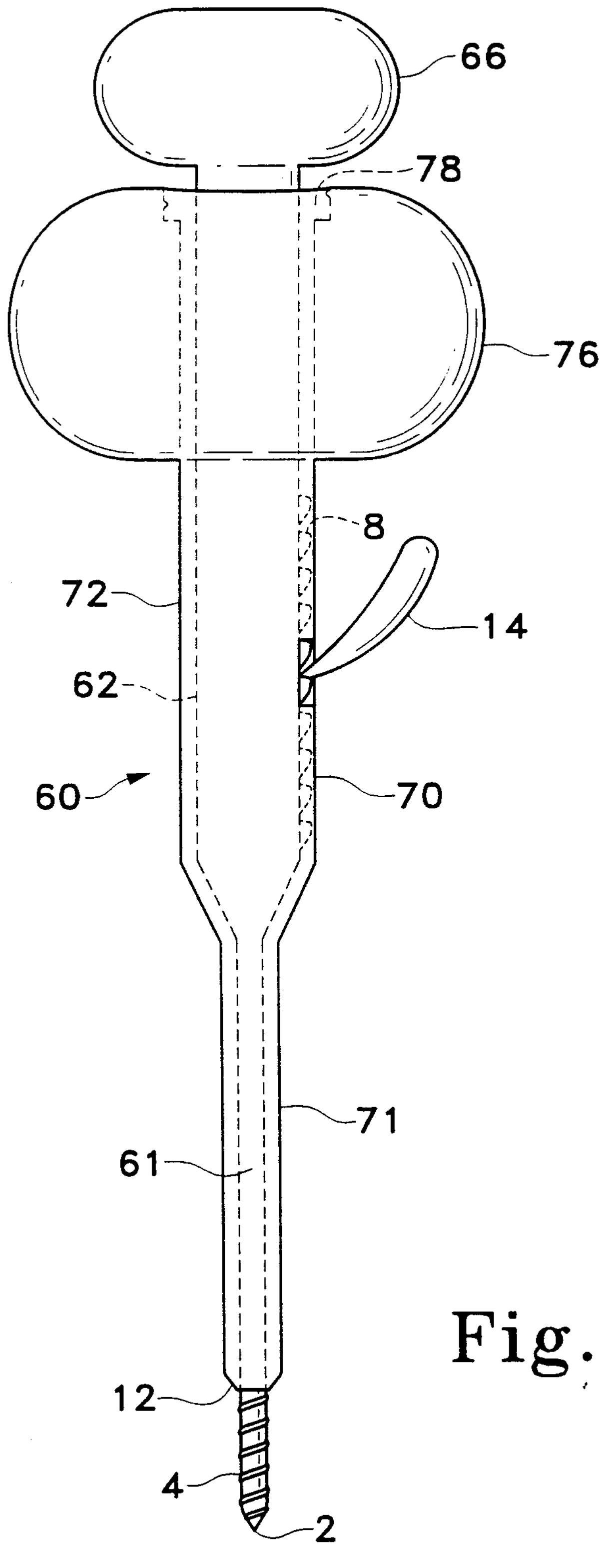

Fig. 5

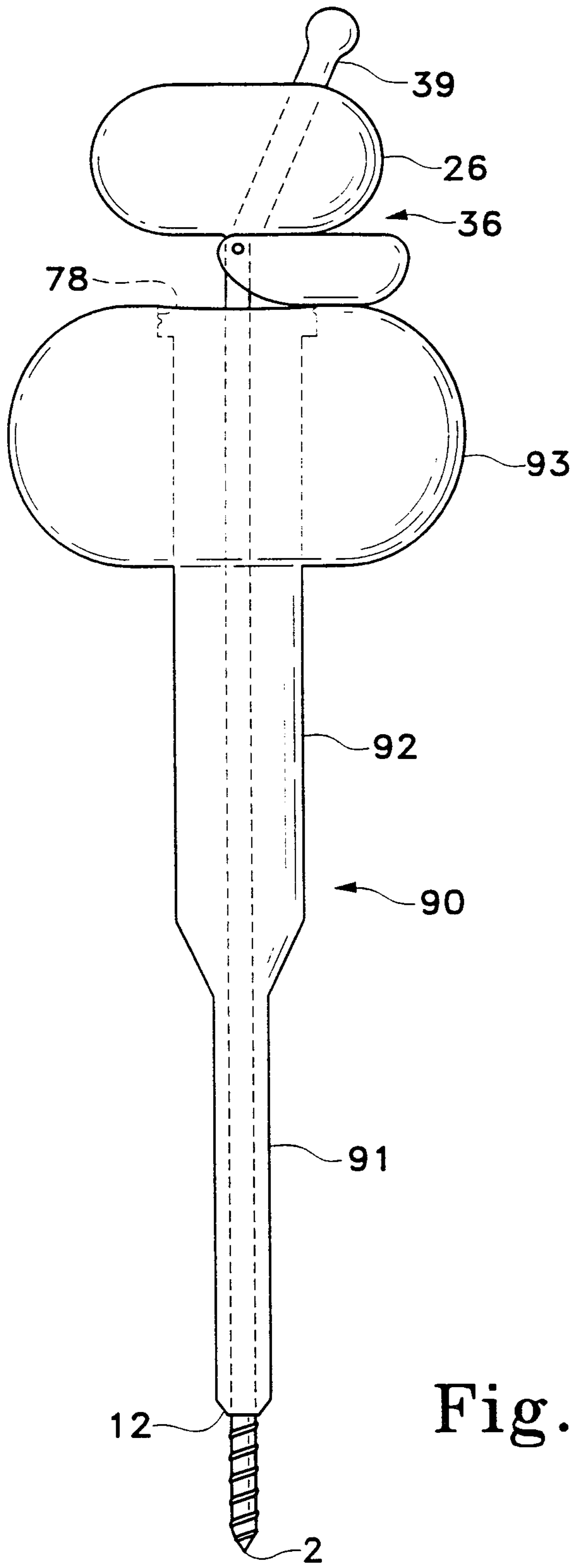

Fig. 6

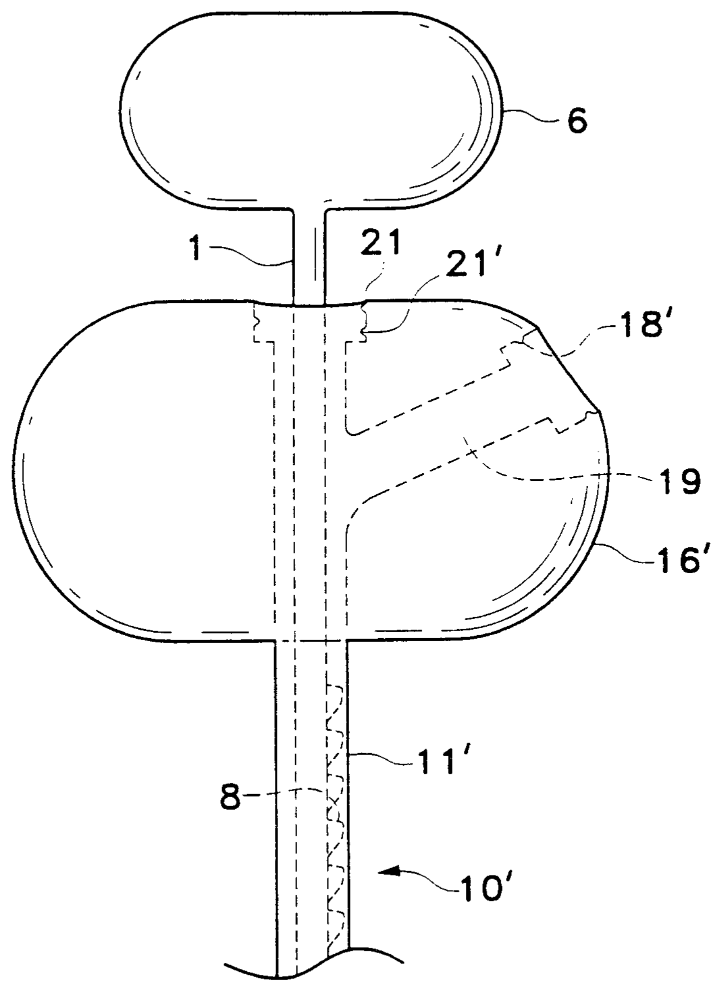

Fig. 7

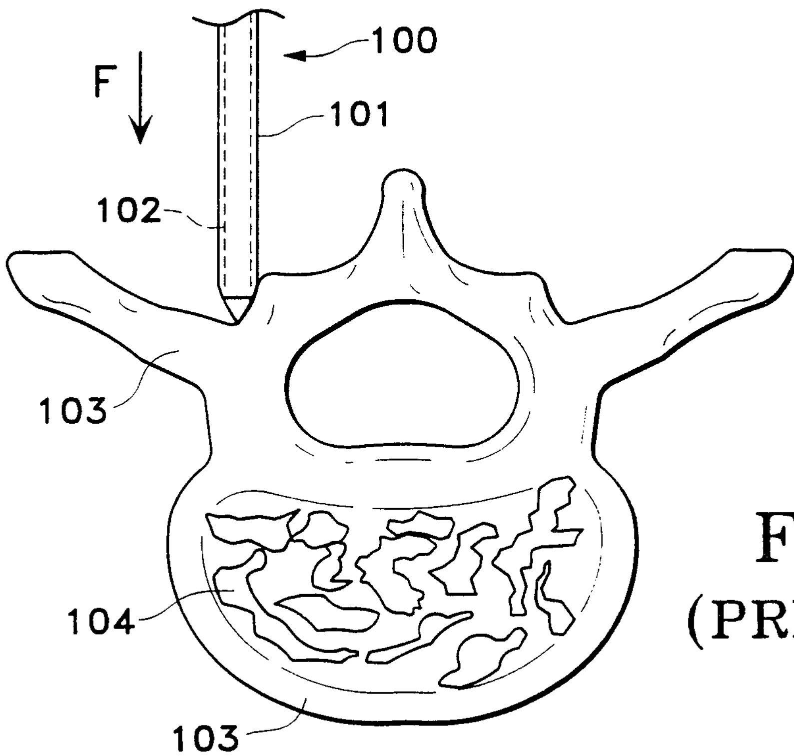

Fig. 8
(PRIOR ART)

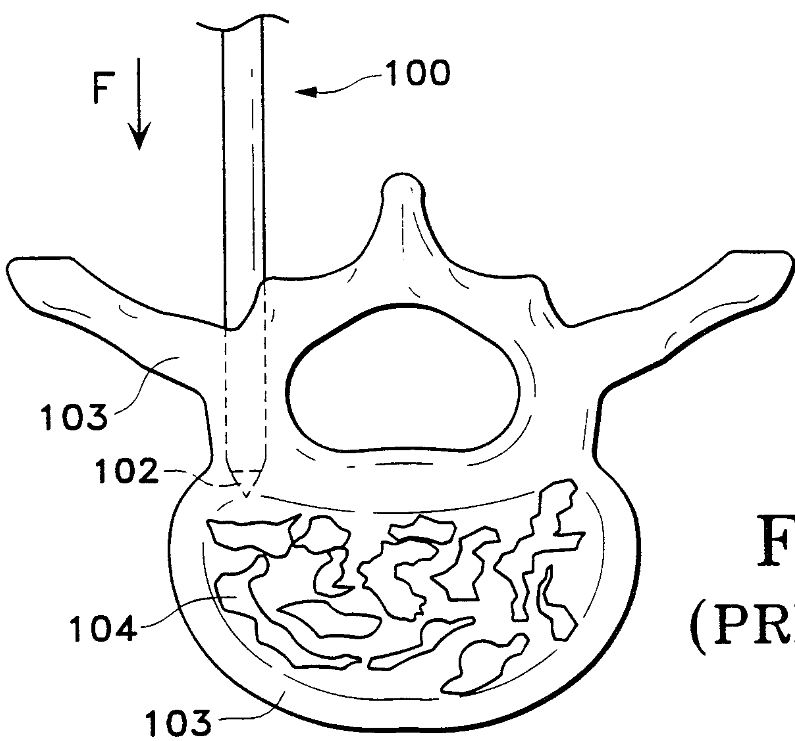

Fig. 9
(PRIOR ART)

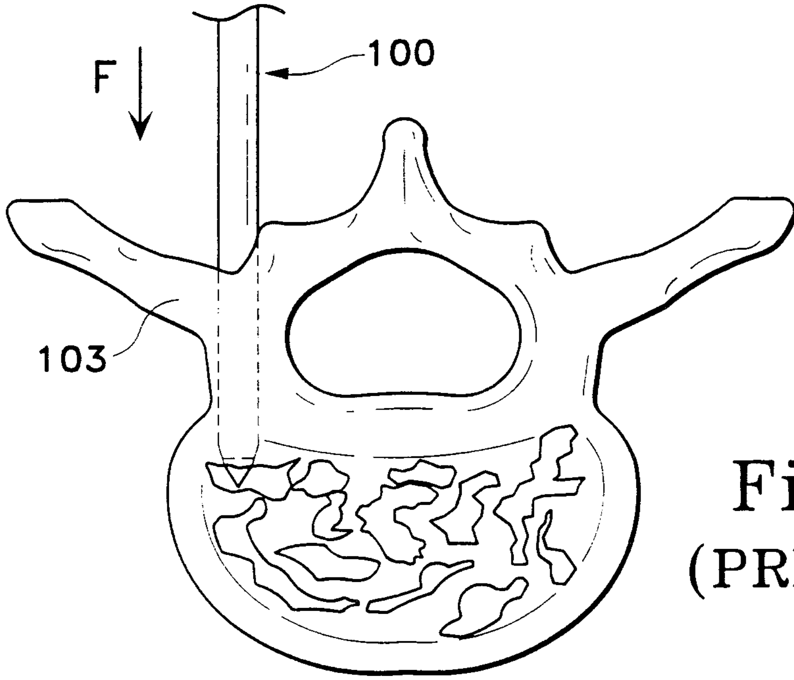

Fig. 10
(PRIOR ART)

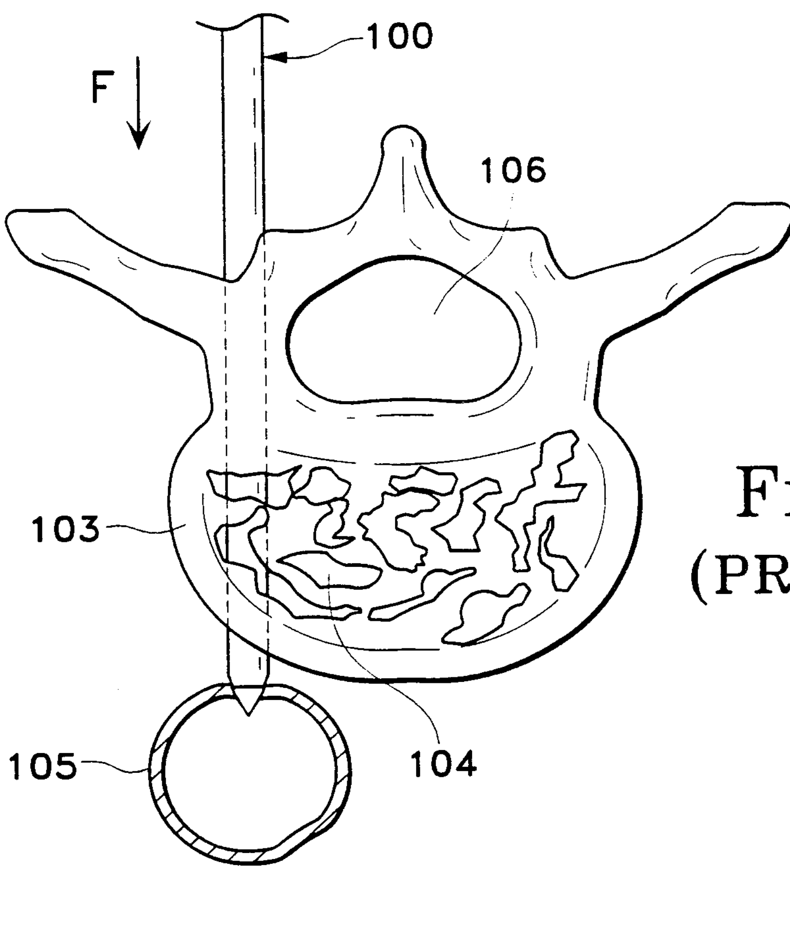

Fig. 11
(PRIOR ART)

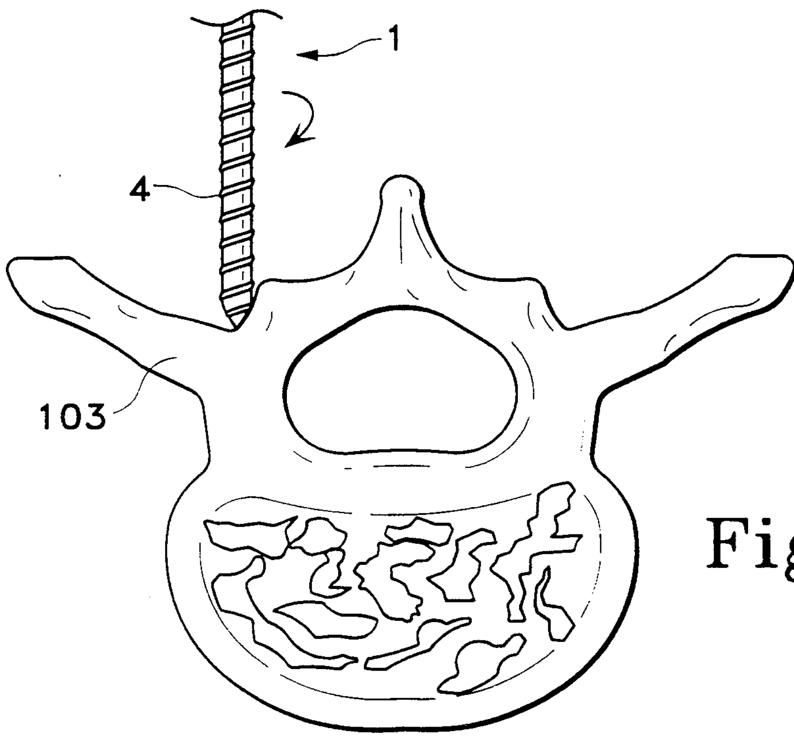

Fig. 12

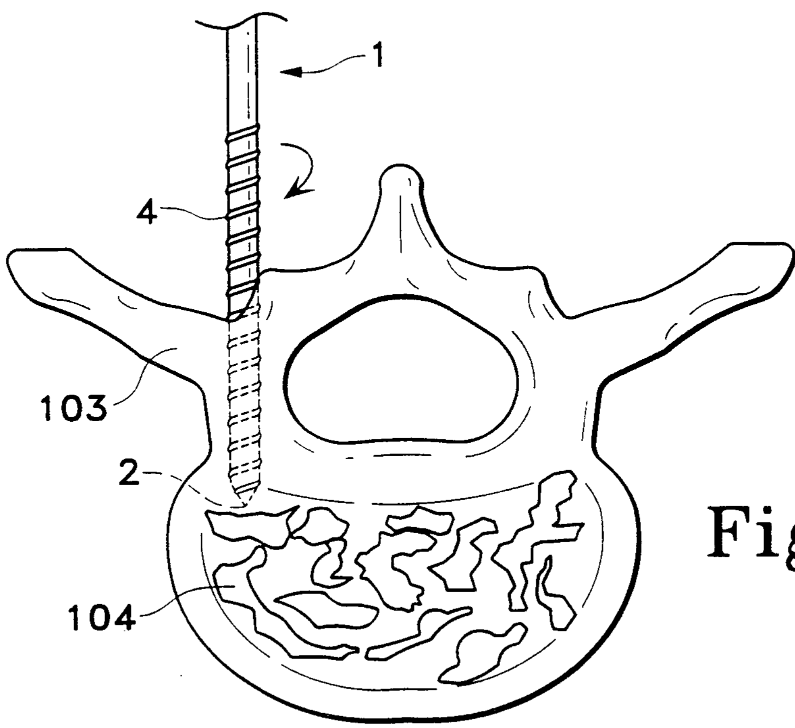

Fig. 13

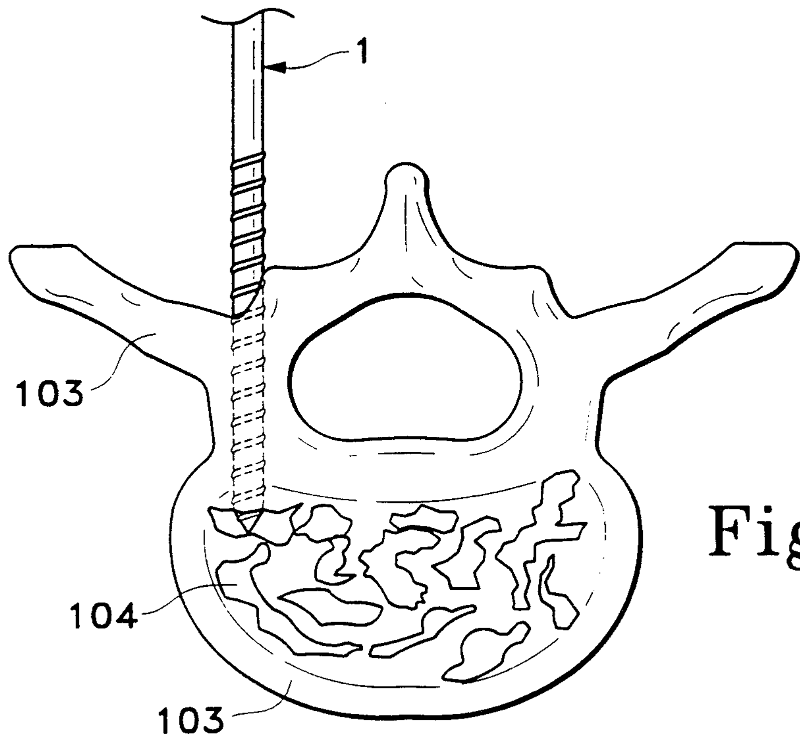

Fig. 14

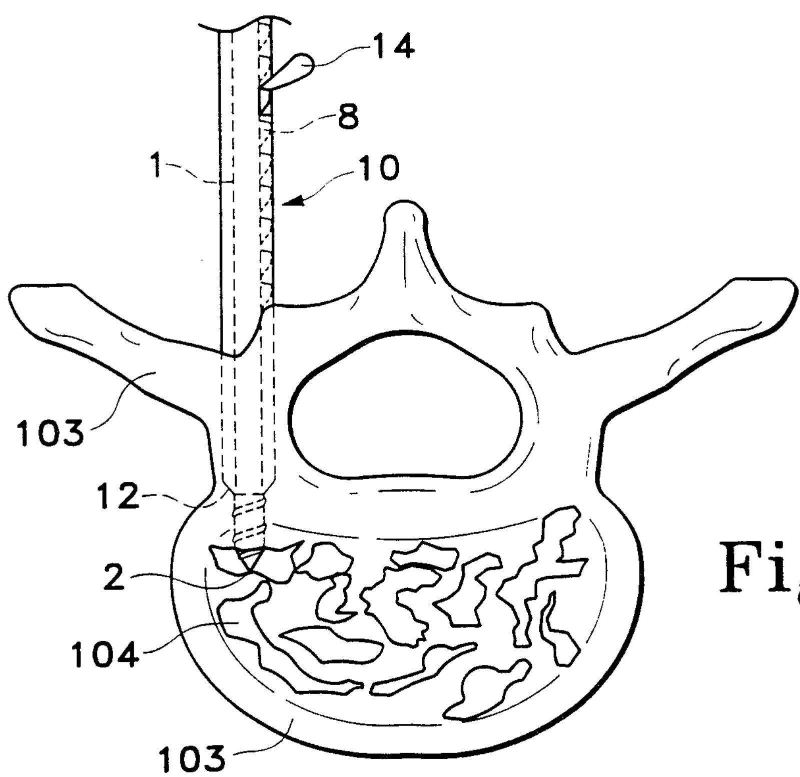

Fig. 15

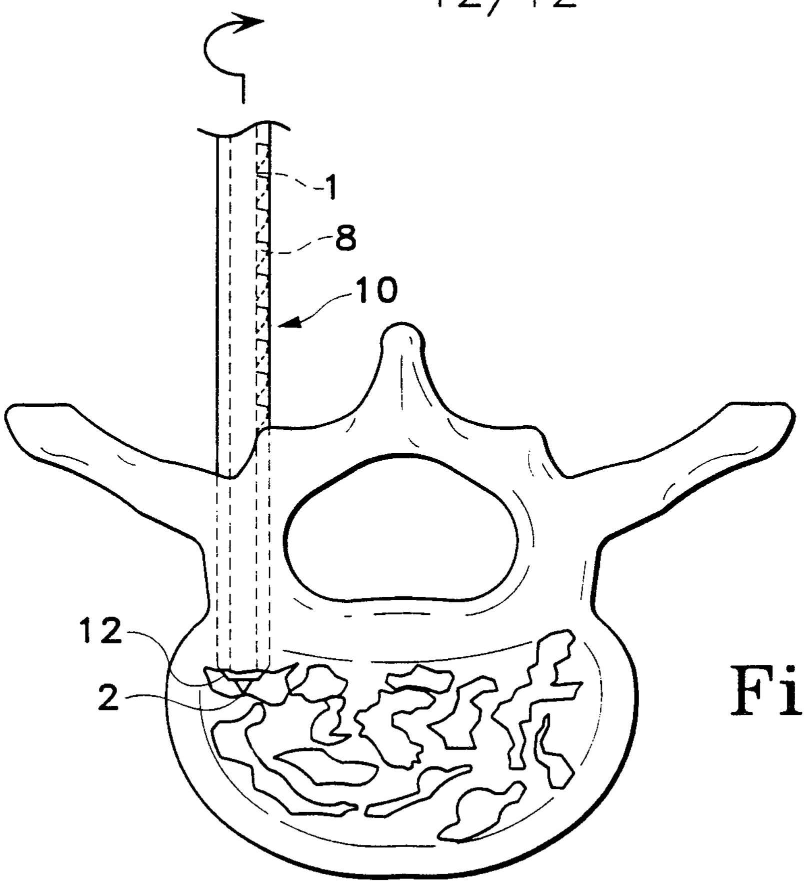

Fig. 16

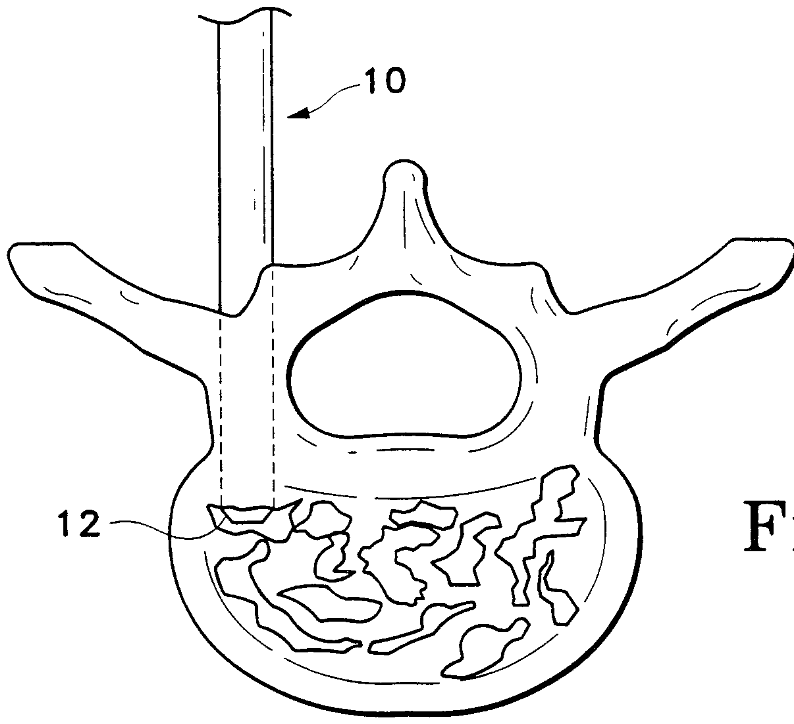

Fig. 17

INTERNATIONAL SEARCH REPORT

Inte onal Application No
PCT/US 98/21662

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/34

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B A61F A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 660 186 A (J.S.BACHIR) 26 August 1997	36-39, 42,43
Y	see column 8, line 53 - column 9, line 44; figure 10	40,41
Y	US 4 793 363 A (R.W.AUSHERMAN AND R.A.BURKHOLDER) 27 December 1988 see column 3, line 41 - column 4, line 4; figure 4	40,41
A	US 5 458 579 A (I.S.CHODOROW AND M.Z.MIRZA) 17 October 1995 see abstract; figures 10,23 see column 5, line 13 - line 39 see column 7, line 4 - line 13	1,3,13, 16

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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Date of the actual completion of the international search	Date of mailing of the international search report
4 February 1999	18/02/1999

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Nice, P

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 98/21662

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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